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Congress of the United States
House of Representatives
Washington, DC 20515–2107

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Dr. Francis Lin
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Petition Seeking Amendment of Food Additive Regulations to Remove Approval for the Use of Bisphenol A in Canned Food Packaging.

The undersigned ("Petitioner") submits this petition, pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 C.F.R. § 171.130, and 21 C.F.R. Part 10. The Petitioner requests that the Food and Drug Administration (FDA) amend 21 C.F.R. § 175.300 to remove canned foods and beverages, especially those designed or intended primarily for children 12 years of age or younger, from the scope of permitted food contact applications for resinous and polymeric coatings containing bisphenol A (BPA). Alternatives to BPA exist and manufacturers have already begun phasing out BPA in the linings of canned food and beverage containers.

Recently, the FDA opened a comment period for an American Chemistry Council (ACC) petition that requests removal of infant feeding bottles and spill-proof "sippy" cups from the scope of permitted food contact applications for polycarbonate resins containing BPA on the grounds that these uses have been abandoned by major manufacturers of baby bottles and sippy cups.[1] Although the Petitioner concurs with the goals of this petition, the Petitioner also believes the rationale used in the ACC petition can be extended to support a prohibition on BPA in canned food and beverage containers.

I. Background on FDA Regulation of BPA

BPA (4,4'-isopropylidenediphenol; CAS Reg. No. 80-05-7) is regulated for use as a monomer in the manufacture of polycarbonate and epoxy-based enamels and coatings used in food contact applications. Specific regulations which mention BPA as a monomer used in the production of food additives include 21 C.F.R. § 172.105 (anoxomer), § 175.300 (resinous and polymeric coatings), § 177.1580 (polycarbonate resins),

[1] See http://plastics.americanchemistry.com/Product-Groups-and-Stats/PolycarbonateBPA-Global-Group/FDA-Petition-Letter-ACC.pdf.

§ 177.1585 (polyestercarbonate resins), § 177.2600 (rubber articles intended for repeated use), § 177.2280 (4,4′-isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins), § 177.2420 (cross-linked polyester resins), § 177.1655 (polysulfone resins), and § 177.1440 (4,4′-isopropylidenediphenol-epichlorohydrin resins with a minimum molecular weight of 10,000).

The regulations detailed above permit any manufacturer or processor to manufacture and market a food contact article made from BPA as long as the conditions of use and specifications, such as identity and extractable limitations, in the applicable regulation(s) are met. For example, section 175.300 broadly permits resins and polymeric coatings to be used "as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food," provided that the resins and coatings are produced in accordance with the regulation and meet applicable specifications and extractives limitations. Historically, epoxy resins and coatings made with BPA have been used in the lining of metal food and beverage containers.

21 C.F.R. § 175.300 should be amended, as requested below, to reflect new information showing that many product manufacturers have intentionally and permanently begun to abandon the use of resinous and polymeric coatings containing BPA in linings of cans of infant formula and baby and toddler food. The same consumer preferences for alternatives to BPA that have driven the elimination of BPA from baby bottles and sippy cups as described in the ACC petition also have led to a reduction in its use in other canned food and beverage products. Pursuant to 21 C.F.R § 171.130, I petition the Commissioner to revoke all regulations permitting the use of a food additive that results in BPA becoming a component of canned food or beverages.

II. Product Manufacturers are Phasing Out the Use of Resins Containing BPA in All Food and Beverage Cans

Under 21 C.F.R. § 171.130, any interested person is permitted to file a petition to "propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive." The petition may be based on "an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal."[2]

[2] 21 C.F.R. § 171.130(b)

Because BPA is an unstable polymer and is also lipophilic (fat-seeking), it can leach from packaging into canned foods,[3] and other food products.[4] Once in food, BPA can move quickly into people—a particular concern for women of childbearing age and for young children. Despite the fact that BPA has been largely removed from baby bottles and sippy cups, the chemical's pervasive presence in food and beverage packaging and ability to readily leach into food results in estimates of 93 percent of the U.S. population having detectable levels of BPA in their bodies.[5] Studies have suggested that BPA in food packaging is the most significant sources of exposure to this chemical.[6]

BPA is a well-documented endocrine-disrupting chemical that can mimic action of the hormone estrogen.[7] Recent scientific data also shows that BPA can interfere with the thyroid hormone, which is important for neurodevelopment in fetuses, infants and children.[8] Over 200 scientific studies show that exposure to BPA, particularly during prenatal development and early infancy, are associated with a wide range of adverse health effects in later life. Studies have found that BPA is associated with an increased risk for cardiovascular disease, miscarriages, breast and prostate cancer, reproductive dysfunction, metabolic dysfunction, and neurological and behavioral disorders.[9] These scientific findings led both the National Toxicology Program at the National Institutes of Health and the FDA to express some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.[10] BPA has been found in blood[11] and urine[12] of pregnant women and in breast milk soon after

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[3] Noonan GO, Ackerman LK, Begley TH (2011). Concentration of bisphenol A in highly consumed canned foods on the U.S. market. Journal of Food and Agricultural Chemistry (in press): DOI: 10.1021/jf201076f. See also Brotons JA, Olea-Serrano MF, Villalobos M, et al. (1995). Xenoestrogens released from lacquer coatings in food cans. Environ Health Perspect, 103:608-612.

[4] Schecter A, Malik N, Haffner D et al. (2010). Bisphenol A (BPA) in U.S. Food. Environmental Science and Technology 44: 9425-9430.

[5] 2003-2004 National Health and Nutrition Examination Survey (NHANES III) conducted by the Centers for Disease Control and Prevention (CDC) found detectable levels of BPA in 93% of 2517 urine samples from people six years of age and older.

[6] Rudel R, Gray J, Engel C, et al. (2011). Food Packaging and Bisphenol A and Bis(2-Ethyhexyl) Phthalate Exposure: Findings from a Dietary Intervention. Environ Health Perspect. 119: 914-919.

[7] NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A, NIH Publication No. 08 – 5994 (9/2008) (http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf).

[8] Kaneko M, et al. Bisphenol A acts differently from and independently of thyroid hormone in suppressing thyrotropin release from the bullfrog pituitary. Gen Comp Endocrinol. 2008 155(3):574-80. Zoeller RT. Environmental chemicals impacting the thyroid: targets and consequences. Thyroid. 2007. 17(9):811-7.

[9] Braun JM, Yolton K, Dietrich KN, et al. (2009). Prenatal bisphenol A exposure and early childhood behavior. Environ Health Perspect, 117:1945-1952; Lang IA, Galloway TS, Scarlett A, et al. (2008). Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. J Am Med Assoc, 300:1303-1310; Prins GS, et al. Developmental exposure to bisphenol A increases prostate cancer susceptibility in adult rats: epigenetic mode of action is implicated. Fertil Steril. 2008 Feb;89(2 Suppl) e 41, doi:10.1093/humrep/dep381.

[10] See http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm

[11] Padmanabhan V, Siefert K, Ransom S, et al. (2008). Maternal bisphenol-A levels at delivery: A looming problem? J Perinatol, 28:258-263.

[12] Ye X, Bishop AM, Reidy JA, et al. (2006a). Parabens as urinary biomarkers of exposure in humans. Environ Health Perspect, 114: 843-1846.

women gave birth.[13] BPA also has been found in blood samples from developing fetuses as well as the surrounding amniotic fluid,[14] and it has been measured in placental tissue and umbilical cord blood at birth[15] as well as in the urine of premature infants housed in neonatal intensive care units.[16] These data indicate that pregnant women exposed to BPA can easily pass this chemical to their children during pregnancy or breastfeeding and further illustrate why this petition is seeking to ban the use of BPA in canned food.

Although BPA has been phased out of small reusable household food and beverage containers, infant formula cans and baby and toddler food, there are a number of other food and beverage packaging materials, including cans of food (some of which are designed or intended for children under the age of 12) that do contain BPA. However, largely because of consumer demand, many manufactures have already implemented a switch away from the use of BPA in their canned food linings. The development of BPA-free liners is becoming a practical and economical choice for manufacturers. For example:

- In 2009, Heinz began phase out of BPA from all canned foods prioritizing elimination of BPA from infant foods. The company states: "Heinz also is pleased to be recognized for our leadership in moving to alternative materials that are Bisphenol A (BPA) free. Heinz has been a leader in food safety ever since our founder started this company in 1869." [17]

- In 1999, Eden Organic eliminated the use of BPA in cans of beans. Eden states "All Eden Organic Beans, Refried Beans, Chilies and Rice & Beans are cooked in steel cans coated with a baked on oleoresinous c-enamel that does not contain the endocrine disrupter chemical, bisphenol-A (BPA).[18]

- Earlier this year, Kroger made an announcement that they will ban BPA from its corporate brand canned foods and from all baby products it sells. The company states, "Kroger recognizes that Bisphenol A (BPA) is perceived as a chemical of concern by some customers…Kroger has begun a process that we believe will result in the removal of BPA in the linings of canned goods in all of our corporate brand items."[19]

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[13] Kuruto-Niwa R, Tateoka Y, Usuki Y, et al. (2006). Measurement of bisphenol A concentration in human colostrum. Chemosphere, 66: 1160-1164.
[14] Ikezuki Y, Tsutsumi O, Takai Y, et al. (2002). Determination of bisphenol A concentrations in human biological fluids reveals significant early prenatal exposure. Hum Reprod, 17:2839-2841.
[15] Schonfelder G, Wittfoht W, Hopp H, et al. (2002). Parent Bisphenol A accumulation in the human maternal-fetal-placental unit. Environ Health Perspect, 110:A703-707; Environmental Working Group (2009) Pollution in minority newborns (www.ewg.org/minoritycordblood/home).
[16] Calafat AM, Weuve J, Ye X, et al. (2009). Exposure to bisphenol A and other phenols in neonatal intensive care unit premature infants. Environ Health Perspect, 117:639-644.
[17] www.heinz.com/CSR2009/social/business/food_safety.aspx
[18] http://www.edenfoods.com/articles/view.php?articles_id=178
[19] http://www.thekrogerco.com/documents/Kroger%20Information%20on%20BPA.pdf

- Muir Glen states, "Muir Glen has been working diligently with our can suppliers to develop and test alternative linings that do not use BPA, and we have successfully identified and tested an alternative that has proven safe and viable in our processing of tomatoes."[20]

- ConAgra "has begun packaging some products, specifically tomatoes, in non-BPA lined cans, and we will continue to evaluate non-BPA liners for the remainder of our canned-product portfolio.[21]

- Earlier this month, Campbell's announced that they are going BPA-free stating: "We have already started using alternatives to BPA in some of our soup packaging and we are working to phase out the use of BPA in the lining of all of our canned products. The cost of this effort is not expected to be material."[22]

This public data was further substantiated when in March 2012, a survey was taken by the Petitioner of all the top selling identifiable manufactures of canned food and beverage goods (see Attachment 1 for responses from manufacturers). From company responses received to date, the Petitioner learned that:

- Del Monte Foods has "already transitioned to BPA-free linings for some of our tomato, vegetable and fruit products"
- Roll Global LLC, with operating companies that include POM Wonderful and FIJI Water, do "not currently use BPA in the plastic containers of its beverage products."
- In addition to Campbell's public announcement regarding phasing out BPA in canned products, Campbell does "not use BPA in our non-metal packaging."
- Smuckers® responded that "our proactive effort to identify BPA alternatives began more than four years ago....as a result, all of our plastic packaging is now made with BPA alternatives."

In today's marketplace BPA can liners are actively being removed from the market and are already eliminated from some brands and types of products. Much like other choices to remove BPA from certain products, there is nothing to suggest that the phase out of BPA from cans is a temporary condition. Rather, the industry, in response to consumer preference, has made an affirmative decision to discontinue the use of BPA in these products and transition to materials that are BPA-free. The Petitioner is in the process of obtaining additional data from manufacturers regarding the use of BPA in their canned food and beverage products and will submit that data to the FDA when it is available.

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[20] http://www.muirglen.com/news/n-10.aspx
[21] http://company.conagrafoods.com/phoenix.zhtml?c=202310&p=sustainablepackaging
[22] http://www.forbes.com/sites/amywestervelt/2012/03/05/under-pressure-from-parents-advocacy-groups-campbells-goes-bpa-free/

III. Conclusion and Proposed Amendment

In light of the above information, the Petitioner respectfully requests that FDA amend its regulations to prohibit the use of BPA in all canned food and beverage products, particularly those designed or intended primarily for children 12 years of age or younger, as alternatives to the use of BPA in those products exist and are being adopted by a growing number of manufacturers. This amendment would have the effect of precluding the use of BPA-containing coatings and resins in these products and reflect actions and decisions taken by major manufacturers to abandon such use in light of consumer concerns.

IV. Environmental Impact

This petition requests action to prohibit the use of a substance in food packaging and is therefore categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement under 21 C.F.R. § 25.32(m).

Respectfully submitted,

Edward J. Markey